

DEC 15 2003

K032902

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### 510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: September 13, 2003

Applicant: Futura Biomedical  
990 Park Center Drive  
Vista, CA 92081

Telephone: 760-599-1670

Fax: 760-599-1675

Contact: Louise M. Focht

Device Name:	Subtalar Arthrorisis Implant
Device Trade Name:	Subtalar Arthrorisis Implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3040
Product Code:	87 HWC
Predicate Device:	K001231 – The New Deal Kalix Implant
Registration Number:	2030833
Owner Operator Number:	9028319

### Device Description:

The Futura Biomedical Implant is a one-piece device made of Titanium (6AL-4V ELI) intended to be implanted into the sinus tarsi of the foot. The implant is designed in 6 sizes. The implant which is used in the treatment of excessive motion of the talus relative to the calcaneus acts as a spacer for the joint, maintaining the joint space, allowing for range of motion, but limiting excessive pronation.

### Indications for Use:

The Futura Biomedical Arthrorisis Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:

Flat foot treatment in children and adolescents

Congenital flat foot  
 Unsuccessful long term orthopaedic treatment (shoes, insoles...)  
 Tarsal coalitions  
 Painful flat foot  
 Supple deformity in posterior tibial tendon dysfunction  
 Paralytic flat foot  
 Subtalar instability

### Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the New Deal Kalix Implant.

Regulatory Class: II  
 Product Code: 87 KXE

Table I. Comparison of Futura Biomedical and New Deal Kalix Implant

<i>Item</i>	<i>Futura Product</i>	<i>New Deal Product</i>
Product Name	Subtalar Arthrorisis Implant	Subtalar Arthrorisiss Implant
Use	Single use	Single use
Fixation	Screw	Screw
Constraint	Non constrained	non constrained
Material	Titanium 6AL-4V ELI	Titanium alloy and UHMWPE
Sizes	6 sizes	5 sizes
Indications for use	<p>The Futura Biomedical Arthrorisis Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:</p> <p>Flat foot treatment in children and adolescents            Congenital flat foot            Unsuccessful long term orthopaedic treatment (shoes, insoles...)            Tarsal coalitions            Painful flat foot            Supple deformity in posterior tibial tendon dysfunction            Paralytic flat foot            Subtalar instability</p>	<p>The New Deal Kalix implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:</p> <p>Flat foot treatment in children and adolescents            Congenital flat foot            Unsuccessful long term orthopaedic treatment (shoes, insoles...)            Tarsal coalitions            Painful flat foot            Supple deformity in posterior tibial tendon dysfunction            Paralytic flat foot            Subtalar instability</p>

Similarities of the Futura Biomedical Subtalar Arthrorisis Implant and the New Deal Kalix Implant include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; both devices are placed into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation and resulting sequela; both devices are made of industry standard materials, no new materials are introduced in either product; Both devices are comparably sized; both devices have the same indications for use.

**Summary:**

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.



DEC 15 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Louise M. Focht  
Futura Biomedical  
990 Park Center Drive, Suite H  
Vista, California 92081

Re: K032902  
Trade/Device Name: Subtalar Arthrorisis Implant  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: September 16, 2003  
Received: September 17, 2003

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

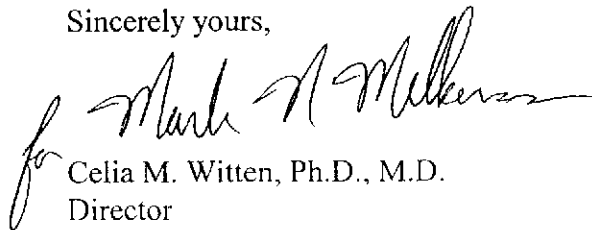
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Louise M. Focht

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510 (k) Number (If Known): K032902  
Device Name: Subtalar Arthrorisis Implant

**Indications for Use:**

The Futura Biomedical Arthrorisis Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Unsuccessful long term orthopaedic treatment (shoes, insoles...)
- Tarsal coalitions
- Painful flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off  
Division of General, Restorative  
and Neurological Devices  
(2) Number

for Mark N. Millerson  
Division Sign-Off  
Division of General, Restorative  
and Neurological Devices

Number K032902